

REMARKS

The following remarks are offered in complete response to the Office Action dated November 25, 2008. In light of these remark, reexamination and reconsideration are respectfully requested.

Claims 1 and 3-20 are present in this application. Claim 2 has been cancelled and claims 19 and 20 have been added.

Claim 1 has been amended to recite elements to provide antecedent basis for claims that depend from Claim 1 and to incorporate the elements of claim 2. Support for this amendment is found in the specification at least on page 6, lines 20-24 and page 13, lines 17-20. Claim 3 has been amended to delete the groove being on the inner surface of the needle, as this is redundant with claim 1. Claims 4-13, 15 and 16 have been amended to clarify claim language and to recite proper antecedent basis. Claim 14 has been amended to recite elements related to the opening between the groove and the tapered ends of the shafts. Support for this is found in the specification at least on page 13, lines 17-20. Claim 18 has been amended to depend from claim 5 and to have proper antecedent basis.

Claims 19 and 20 have been added. Claim 19 is analogous to claim 6 and recites elements deleted in claim 6. Claim 20 is analogous to claim 7 and depends from claim 19.

No new matter has been added in making these amendments.

35 U.S.C. §112 second paragraph Indefiniteness Rejection

Claims 16 and 18 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which that applicant regards as the invention.

The Office Action indicates that claim 16 recites "the suture needle is a cylindrical shaft having a uniform diameter" but it is unclear how it can have a uniform diameter when it tapers at its ends, as recited in claim 1.

Claim 16 has been amended to recite that the shaft, excluding the tapering ends of the needle shaft, is cylindrical and has a uniform diameter.

Claim 18 is considered by the Office Action as being indefinite because the recitation of "at such distance from the tip of the suture needle where the diameter of the tapering ends is equal to the diameter of the narrow suture" is allegedly unclear as to what the distance and diameter is.

Claim 18 has been amended to clarify the claim and specifies both the distance and the diameter.

The Office Action notes that the limitation "the form of the crimp or plug" in Claim 12 does not have antecedent basis.

Claim 12 has been amended to have proper antecedent basis.

Amended claims 12, 16 and 18 particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Applicants therefore request the withdrawal of the rejections of these claims.

35 U.S.C. §102 prior art rejections

Claims 1, 3-11, 14 and 15 have been rejected under 35 U.S.C. §102(b) as being anticipated by DE 19706086.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (MPEP 2131).

Claim 1, the independent claim, has been amended to incorporate the elements of Claim 2, where the suture is secured to the needle through the hole in the shaft of the needle by a means for fastening, where the means for fastening comprise a crimp or plug, into Claim 1. Claim 2 was not anticipated by DE 19706086. Therefore with the incorporation of the elements of Claim 2 into Claim 1, Claim 1 is not anticipated, because DE 19706086 does not teach the elements previously found in Claim 2.

Applicants therefore request the withdrawal of these rejections under 35 U.S.C. §102(b).

35 U.S.C. §103(a) Obviousness Rejections

1. Claims 2, 12 and 13 have been rejected under 35 U.S.C. §103(a) as unpatentable over DE 19706086 in view of U.S. Patent No. 2,199,025.

Claim 2 has been incorporated into claim 1. Applicants respectfully submit that the newly added claims are not obvious over DE 19706086 in view of U.S. Patent No. 2,199,025.

To establish a *prima facie* case of obviousness, three basic criteria must be met. (MPEP 2143) First, there must be some suggestion or motivation, either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Office Action acknowledges that DE 19706086 fails to teach the means for fastening being a crimp or plug as recited in claims 2 (1), 12 and 13.

The Office Action indicates that the '025 Patent teaches a surgical incision member comprising a means for fastening being a crimp or plug, as shown in Figure 1, item 10, which is referred to as a suture button. However, the '025 Patent discloses a surgical incision member having a circular disk as a means for fastening the suture to hold the incised wound closed and to prevent the wound from opening. The Office Action indicates that it would have been obvious to modify the means of fastening of the '025 patent into the teachings of DE 19706086 and to retain the cylindrical cavity of the needle in order to enhance the fastening means of the suture so that the suture would not go through the retaining hole in the needle. In making the modification required to use the suture plug of the '025 patent in DE 19706086, the basic principle required in the operation of the prior art invention must be changed to obtain the applicant's invention. As stated in the MPEP, Section 2143.01 VI:

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

Therefore the '025 Patent does not render the claims obvious.

The '025 Patent does not teach or suggest a method for fastening a suture to the needle assembly, as required by the claims of the applicant's invention. A detailed analysis of the '025 Patent also reveals other differences. The '025 Patent discloses a suture button with an underlying sponge rubber cushion which can be used to tie off or fasten the ends of a suture at its points of entry and exit into skin or tissue. The '025 Patent does not disclose or even contemplate a means for fastening a suture to a surgical needle by way of a crimp or plug. The invention of the '025 Patent requires a minimum of two fasteners to secure the suture, where the fasteners are used to ensure that each end of the suture is prevented from being drawn back through the skin or tissue. Consequently, the fastening means disclosed in the reference comprises a flat disc which rests against the surface of skin or tissue and which prevents either end of the suture from being withdrawn through tissue.

In contrast, the applicant's invention provides a means for fastening a suture to a surgical needle. The applicant's invention does not fasten the suture to skin or tissue. The means for fastening comprises a crimp or plug which resides within a cylindrical cavity of the surgical needle with a view to securely fasten the suture to the needle. The crimp or plug achieves this objective by virtue of a secure and resilient fit within the needle cavity. This secure and resilient fit requires that the crimp or plug reside within the cavity itself instead of resting against the surface of the needle. The resilient or interference fit with the cylindrical cavity further ensures that a single crimp or plug fastens the suture to a surgical needle, and that multiple fasteners are not required. The '025 Patent does not teach or suggest that the suture button of their invention be contained within a needle cavity. The invention of

the '025 Patent would be inoperable if the suture button was used as required by the claims of the applicant's invention.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There is no suggestion or motivation in DE 19706086 to modify the connection of the needle with the suture and the '025 Patent is not related to the connection of a suture with the needle. The Office Action indicates that it would have been obvious to enhance the fastening means of the suture into the needle device so that the suture would not go through the retaining hole in the needle. DE 19706086 does not suggest that there is a problem using the fastening means described in their specification. Nor has the Office Action provided a reference that indicates that there was a problem with the fastening method used in DE 19706086 that would motivate one to change the fastener. Therefore there is no motivation or suggestion in DE 19706086 or the '025 Patent to modify their invention to obtain Applicant's invention.

To establish a *prima facie* case of obviousness, there must be a reasonable expectation of success. There is no reasonable expectation of success based on the teachings in DE 19706086 using suture button as described in the '025 Patent would result in the Applicant's invention. As shown above, the use of the suture button, as taught in the '025 Patent requires the use of the suture button to hold sutured skin together. Modifying DE 19706086 with the suture button, as taught by the '025 Patent, would not result in the applicants' invention. In making the

modification required to use the suture plug of the '025 patent in DE 19706086, the basic principle required in the operation of the prior art invention must be changed to obtain the applicant's invention. By changing the basic principle required in the operation of the suture button in the '025 Patent, there could not have been a reasonable expectation of success in obtaining the applicant's invention. Therefore, there was no reasonable expectation of success at the time of the invention that the claimed assembly could be obtained by modifying DE 19706086 using the '025 Patent.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. As indicated in the Office Action, DE 19706086 fails to teach the means for fastening being a crimp or plug as recited in claims. As shown above, the use of the suture button of the '025 Patent requires that the basic principle required in the operation of the prior art invention be changed to obtain the applicant's invention, and that the teachings of the reference is not sufficient to render the claims *prima facie* obvious. Therefore DE 19706086 and the '025 Patent do not teach or suggest all of the claim limitations of the instant claims.

Therefore, in consideration of the foregoing, Applicants respectfully submit that Claims 2, 12 and 13 are not obvious over DE 19706086 in view of U.S. Patent No. 2,199,025, and request that this rejection be withdrawn.

2. Claim 17 has been rejected under 35 U.S.C. §103(a) as unpatentable over DE 19706086 in view of U.S. Patent No. 5,417,699 ("Klein").

The teachings of DE 19706086 were described above.

The Office Action cites Klein for disclosing that the suture needle is composed of titanium. (Fig . 2)

Claim 17 depends from Claim 1. The Office Action has not cited Claim 1 as being obvious over the cited prior art. Absent such a showing, a claim which depends from a claim which is not obvious cannot be obvious. It was shown above that Claim 1 is not obvious over DE 19706086 in view of the '025 Patent. The '699 Patent does not cure any of the deficiencies cited above. Therefore Claim 17 is not obvious over the cited prior art.

Therefore, Applicants respectfully submit that Claim 17 is not obvious over DE 19706086 in view of U.S. Patent No. 5,417,699, and request that this rejection be withdrawn.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions related to this response, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at the below-listed telephone number concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
BUCHANAN INGERSOLL & ROONEY PC

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